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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,546	11/04/2002	Claire Fraser	PP00365.301	9020

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,546	FRASER ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4 and 22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *081208*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 08/12/08 has been entered.

Status of Claims

2) No claims have been amended.

Claims 4 and 22-28 are pending and are under prosecution.

Information Disclosure Statement

3) Acknowledgment is made of Applicants' information disclosure statement filed 08/12/08. The information referred to therein has been considered and a signed copy of the same is attached to this Office Action.

Rejection(s) under 35 U.S.C. § 103

4) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

5) Claims 4, 22-26 and 28 are rejected under 35 U.S.C § 103(a) as being unpatentable over the disclosure print out of the 'Contig295' sequence data from the sequence file 1997-12-15-NM.dbs attached to the Parkhill Declaration (Applicants' IDS filed 08/12/08) in view of the printed output from the NCBI open reading frame finder (see attachment), Sambrook *et al.* (*Molecular Cloning, A Laboratory Manual*, Second Edition, Cold Spring Harbor, pages 17.1-17.44, 1989) and Campbell AM (*In*: *Monoclonal Antibody Technology*. Elsevier Science Publishers, The Netherlands, Chapter 1, pages 1-32, 1984).

The disclosure print out of the 'Contig295' sequence data from the sequence file 1997-12-15-NM.dbs publicly available since 12/15/1997 as provided in the attachment to the Parkhill Declaration discloses the 'Contig295' sequence presented in complementary 3' to 5' comprising therein the ORF at bases 10544-9642 of the frame one of the complement. See attachment. This disclosure does not disclose a purified polypeptide comprising a 10 to 20 amino acid-long fragment of SEQ ID NO: 2536.

However, the printed translation output of frame one of the 10544-9642 complement of the 'Contig295' obtained from ExPASy website shows the amino acid composition of a protein that comprises 10, 20 or more contiguous amino acids of the instant recited SEQ ID NO: 2536. See the highlighted area in the attachment entitled 'Translate Tool – Results of translation'.

The printed output obtained from the NCBI ORF Finder shows the existence of an ORF at bases 10544-9642 of the frame one complement of Contig295. See the highlighted area in the attachment entitled 'NCBI ORF Finder'.

It was routine and conventional in the art at the time of the invention to express an ORF from a Contig gene sequence obtained from a bacterial pathogen using a recombinant expression technique such as the one described by Sambrook *et al.* Sambrook *et al.* taught that given a known DNA sequence encoding a protein of interest, large amounts of the protein fused, for example with beta-galactosidase, can be made in *E. coli* using standard art known techniques and that such proteins are useful for generating antibodies. See page 17.29, first, second and third full paragraphs; and pages 17.3-17.9.1.

Campbell taught that it is customary now for any group working on a macromolecule to both clone the genes coding for it and make antibodies to it sometimes without a clear objective for their application. Campbell also taught that protein macromolecules can be studied in the field of research using these antibodies. See page 29, last paragraph.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to obtain Contig295's ORF at bases 10544-9642 of the frame one complement using publicly available ORF finders such as NCBI ORF Finder and express it in a purified form using an art-known recombinant technique taught by Sambrook *et al.* to produce the purified protein of the instant invention. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of producing an antibody to the expressed protein macromolecule in order to study the protein for research purposes since antibodies are made to a protein sometimes without a clear objective for their application as taught by Campbell.

Claims 4, 22-26 and 28 are *prima facie* obvious over the prior art of record.

6) Claim 27 is rejected under 35 U.S.C § 103(a) as being unpatentable over the disclosure print out of the 'Contig295' sequence data from the sequence file 1997-12-15-NM.dbs from the Parkhill Declaration (Applicants' IDS filed 08/12/08) as modified by the printed output from the NCBI open reading frame finder (see attachment) and the printed output from the NCBI open reading frame finder (see attachment) as applied to claim 4 above.

The teachings of the disclosure print out of the 'Contig295' sequence data from the sequence file 1997-12-15-NM.dbs from the Parkhill Declaration as modified by Sambrook *et al.* and Campbell AM are explained above, which do not disclose the presence of a pharmaceutically acceptable carrier.

However, adding a pharmaceutically acceptable carrier to a prior art purified protein is routine and very conventionally practiced in the art especially when raising antibodies to the fusion protein. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add an art-known pharmaceutical carrier to the prior art purified protein to produce the instant invention

with a reasonable expectation of success, since it is quite conventional to have such a fusion protein mixed with in a pharmaceutical carrier before generating specific antibodies.

Claim 27 is *prima facie* obvious over the prior art of record.

Remarks

7) Claims 4 and 22-28 stand rejected.

8) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

9) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

10) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
S. Devi, Ph.D
Primary Examiner
AU 1645

October, 2008